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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,365	03/09/2001	Martha Jo Whitehouse	PP01671.003	8316

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	9

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.	Applicant(s)
09/802,365	Whitehouse
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 5, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5, 6*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of the species of FGF set forth in SEQ ID NO:4, in Paper No.8, filed on 05 August 2002 is acknowledged.

The traversal is that the FGF-2 of SEQ ID Nos: 2 and 4, are structurally similar, differing only by two amino acid residues (positions 112 and 128) and carry out similar functions. Thus Applicants request the examination of the two species of FGF-2, since it would present an undue burden to search these two species.

This ground of traversal is found persuasive, therefore, the methods using the FGF-2 of SEQ ID Nos: 2 or 4 will be searched and examined.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims will be searched and examined so far as they relate to a method of using the FGFs of SEQ ID Nos:2 or 4.

Specification

2a. The disclosure is objected to, because it contains an embedded hyperlink and/ or other forms of browser-executable code.

Page 11, line 10, of the instant specification contain hyperlink which must be deleted. Please examine the specification carefully for any other hyperlinks in the text and delete them. Applicants is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

2b. The abstract of the disclosure is objected to because it comprises two paragraphs. Abstract must comprise only one paragraph. Correction is required. See MPEP § 608.01(b).

Claim objections

3. Claims 1, 6, 16, are objected to because of the following informalities:

Claims 1, 6, 16 objected to because they recite non-elected species.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. §112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

4a. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Instant claims 1-29 are drawn to a method for treating, improving or preventing erectile dysfunction, said method comprising administering a therapeutically effective amount of basic fibroblast growth factor (FGF), comprising the amino acid sequence set forth in SEQ ID NO:2 or 4, however, the specification does not provide any guidance of how to use FGF to treat or prevent erectile dysfunction, because it does not disclose one single case where erectile dysfunction is treated or prevented using FGF. Instant specification asserts that the method of the invention utilizes angiogenic agents or growth factors to encourage endothelial cell proliferation, to restore endothelial cell function and to promote angiogenesis, particularly to promote blood floe, (see page 3, lines 25-

30). However, beyond this mere statement, instant specification does not present any data showing that the administration of FGF does treat or prevent erectile dysfunction. Penile erection involves a complex interaction between the CNS and local factors. It is a neurovascular event modulated by psychological and hormonal factors, (see Thomas, Japanese journal of pharmacology, Vol.89, pages 101-112, especially abstract and table 4). Furthermore, there are many disease conditions that are associated with erectile dysfunction, such as heart disease, peripheral vascular disease, diabetes mellitus, thus the agent to be used for erectile dysfunction must also not have any detrimental effects on the patient. Therefore, an agent to be effective in treating or preventing this dysfunction, said agent must be tested in an appropriate model to establish its effectiveness. Without conducting appropriate experiments and using appropriate controls, one can not assert that erectile dysfunction is treated or prevented based on hypothesis. Example 1 on page 22, line 25-29 of the instant specification discloses dosages of recombinant FGF to be employed in phase I clinical trials, and Example 2, on page 23 discloses formulations and dosages of recombinant FGF administered to humans. While these two examples disclose formulations, dosages and storage instructions, it appears that these dosages were not actually used in humans or in any experimental trials, therefore, it is not predicable whether the dosages of FGF disclosed, or any dose of FGF for that matter, would treat, improve or prevent erectile dysfunction, since the specification discloses no evidence to support said assertion.

Thus, Applicants are non-enabling for a method for treating, improving or preventing erectile dysfunction, said method comprising administering a therapeutically effective amount of basic

fibroblast growth factor (FGF), comprising the amino acid sequence set forth in SEQ ID NO:2 or 4.

4b. Claims 6-14 and 21-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6-14 and 21-29 are drawn to a method for treating, improving or preventing erectile dysfunction, said method comprising administering a therapeutically effective amount of a biologically active fragment or mutein of the FGF of SEQ ID NO:2 or 4, however, the structure of biologically active fragments or muteins are not defined. The written description in this case only discloses the FGF of SEQ ID NO:2 or 4, and thus, the written description is not commensurate in scope with the claims drawn to method for treating, improving or preventing erectile dysfunction, said method comprising administering a therapeutically effective amount of a biologically active fragment or mutein of the FGF of SEQ ID NO:2 or 4. Applicants do not teach which regions of the FGF of SEQ ID NO:2 or 4 are critical for the biological activity. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a mutein or a biologically active fragment of SEQ ID NO:2 or 4, which can be used in a method of treating, improving or preventing erectile dysfunction, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polypeptide, other than that of SEQ ID NO:2 or 4 to be used in the claimed method. The issue here is the breadth of the claims

in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. Therefore, the written description in this case only discloses the FGF of SEQ ID NO:2 or 4 to be used in the method for treating, improving or preventing erectile dysfunction.

Conclusion

5. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wedensday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
04 November 2002

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SUPERVISORY PATENT EXAMINER
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